K 060327

Appendix D: Twin-Pass and Skyway Catheter 510(k) Summary

Common/Usual Name: Intravascular Catheter

APR 12

Product Trade Name: Twin-Pass™ Dual Access Catheter and Skyway™ Support Catheter

Classification Name: Percutaneous Catheter
Product Code: DQY

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369
USA

Establishment Registration: 2134812

Contact: Julie Tapper
Regulatory Affairs Associate
(763) 656-4228 phone
(763) 656-4253 fax

Performance Standards:
No performance standards have been developed under section 514 for this device.

Device Description:
The Twin-Pass™ Dual Access Catheter is a hydrophilically coated, dual lumen catheter designed for use in the arterial vasculature. The catheter provides support for 0.014"/0.36mm guidewires, and the dual lumen design allows for the delivery of a second guidewire into distal vasculature while leaving the initial guidewire in place. The Twin-Pass catheter comes with a stiffening mandrel to provide support and pushability during catheter insertion.

The SKYWAY catheters are single lumen, hydrophilically coated catheters designed for use in the arterial vasculature. The catheters provide support for 0.014"/0.36mm guidewires during interventional procedures, and allow for the exchange of one distally located guidewire for another one while maintaining access to distal vasculature.

Intended Use:
The Twin-Pass catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

The SKYWAY support catheters are intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The Skyway OTW also may be used to subselectively infuse/deliver therapeutic agents.

Summary of Non-Clinical Testing:
Flow-rate testing was conducted using saline and a 76% contrast medium.

Summary of Clinical Testing:
No clinical evaluations of this product were conducted.

Predicate Devices:
The Twin-Pass™ Dual Access Catheter and Skyway™ Support Catheter are substantially equivalent to the Pivot™ Steerable Microcatheter, Twin-Pass™ Dual Access Catheter, Skyway™ Support Catheter, and Langston™ Dual Lumen Pressure Monitoring Catheter.

Conclusions:
The Twin-Pass™ Dual Access Catheter and Skyway Support Catheter are substantially equivalent to the Pivot™ Steerable Microcatheter, Twin-Pass™ Dual Access Catheter, Skyway™ Support Catheter, and Langston™ Dual Lumen Pressure Monitoring Catheter, based on comparisons between the indications for use, construction materials, and device dimensions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Vascular Solutions, Incorporated
c/o Ms. Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K060327
Twin-Pass™ Dual Access Catheter and Skyway™ Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 7, 2006
Received: February 9, 2006

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications For Use Statement
Twin-Pass Dual Access Catheter

510(k) Number: K060327

Device Name: Vascular Solutions Twin-Pass™ Dual Access Catheter

Indications for Use:
The Twin-Pass catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascu

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III. Indications For Use Statement
Skyway Support Catheter

510(k) Number: K060327

Device Name: Vascular Solutions Skyway™ Support Catheter

Indications for Use:
The Skyway support catheters are intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The Skyway OTW also may be used to subselectively infuse/deliver therapeutic agents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060327

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